UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/692,191	10/22/2003	Pamela Cifra	13720-105089US1	8424

65989 7590 08/13/2010

KING & SPALDING
1185 AVENUE OF THE AMERICAS
NEW YORK, NY 10036-4003

EXAMINER	
ROYDS, LESLIE A	

ART UNIT	PAPER NUMBER
1614	

NOTIFICATION DATE	DELIVERY MODE
08/13/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No.	Applicant(s)	
	10/692,191	CIFRA ET AL.	
	Examiner	Art Unit	
	Leslie A. Royds	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *24-28,30,31,33,35,105,107-109,115-117 and 122-124* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *24-28,30,31,33,35,105,107-109,115-117 and 122-124* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20Jul10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 24-28, 30-31, 33, 35, 105, 107-109, 115-117 and 122-124 are presented for examination. Prosecution on the merits of this application is reopened on the instant claims, which are considered unpatentable for the reasons set forth *infra*.

Applicant's submission filed January 28, 2010 has been received and entered into the present application.

Applicant's Information Disclosure Statement (IDS) filed July 20, 2010 has been received and entered into the present application. As reflected by the attached, completed copy of form PTO/SB/08a (two pages total), the Examiner has considered the cited references.

Applicant Interview Regarding Allowable Subject Matter

Several interviews were held the week of August 2, 2010 and the week of August 9, 2010 with Applicant's representative, Joe Eng (Reg. No. 54,084), to discuss a proposed Examiner's Amendment to the claims. Specifically, the proposed amendment(s) constituted an amendment to instant claims 24, 35, 105, 115-117 and 123-124 to amend the upper limit of the range (i.e., in each claim, the upper limit is identified as 10 mM) from 10 mM to 100 mM, to make the claimed range(s) commensurate with the subject matter disclosed in the specification and claims as originally filed. In a telephone conversation Monday, August 9, 2010, Applicant's representative declined to accept the proposed Examiner's amendment.

Due to the fact that the amendment to the claimed range(s) was declined by Applicant, it is understood that Applicant's agreement to the proposed Examiner's Amendment discussed December 11, 2009 (i.e., to remove the term "prevent" from each of instant claims 24, 105 and 115) is now moot.

Accordingly, the claims are not in condition for allowance at the present time for the reasons set forth *infra*.

Applicant's Request to Correct Inventorship under 37 C.F.R. 1.48(b)

Applicant's submission filed March 18, 2010 requested deletion of inventors Pamela Cifra, Michael Dake and Christopher Elkins under 37 C.F.R. 1.48(b) has been received and entered into the present application.

In view of the papers filed March 18, 2010, the inventorship in this nonprovisional application has been changed by the deletion of inventors Pamela Cifra, Michael Dake and Christopher Elkins.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt and correction of Office records to reflect the inventorship as corrected.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description Requirement, New Matter (New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-28, 30-31, 33, 35, 105, 107-109, 115-117 and 122-124 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

In particular, the specification and claims as originally filed fail to provide adequate written support for (1) zinc to be present in the composition in a concentration range from 10 μM to 10 mM (claims 24, 105 and 115), (2) zinc to be present in the composition in a concentration range of 900 μM to 10 mM (claims 35, 116 and 123), or (3) zinc to be present in the composition in a concentration range of 1 mM to 10 mM (claims 117 and 124).

Applicant references Ex.1 and para.[39] in support of the instantly claimed ranges. Specifically, Ex.1 of the instant specification (see, e.g., p.14 *et seq.*) teaches sample stock solutions uses to prepare topical zinc formulations that were then tested to determine the effect of the formulation on skin elasticity, wherein the stock solutions were base only (i.e., no zinc), 10 μM Zn^{2+}, 1.0 mM Zn^{2+} and 100 mM Zn^{2+}. Applicant further discloses at para.[39] that, "For improving elastin or elasticity in the skin, a composition according to this invention contains one or more zinc-containing components in a total concentration of from about 1.0 picomolar (pM) to about 900 μM, preferably from about 100 to about 500 pM. The composition may be applied topically so as to provide an effective amount of zinc to the area where the effect is desired, and may be applied at varying intervals and over varying durations to achieve the desired degree of increase in elastin content."

However, Applicant's broad disclosure of the range of 1.0 pM to about 900 μM, preferably from about 100 to about 500 pM, and the three concentrations of 10 μM Zn^{2+}, 1.0 mM Zn^{2+} and 100 mM Zn^{2+} as described in Ex.1 do not provide clear written description to now claim the use of zinc in a concentration ranging from 10 μM-10 mM (claims 24, 105 and 115), 900 μM-10 mM (claims 35, 116 and 123) or 1 mM-10 mM (claims 117 and 124) because each of such ranges represents a subgenus of values that was not previously set forth or that would have been immediately envisaged by one skilled in the art from the specification and/or claims as originally filed. Despite the fact that Applicant may rely upon the fact that Ex.1 may support a range of from 10 μM-100 mM of zinc to be used in the claimed composition, such disclosure of this broader range of 10 μM-100 mM fails to provide clear written description to derive a subgenus of ranges, i.e., 10 μM-10 mM or 1 mM-10 mM, out of the larger range to define the amount of zinc that Applicant intends to include in the instantly claimed composition. In addition, the specification and/or claims as originally filed fail to provide clear written description of the particular upper limit of 10 mM such that it would have been clear that Applicant was in possession of a zinc concentration ranging from 900 μM-10 mM as now claimed (claims 35, 116 and 123). This represents a narrowing of the

subject matter originally described and claimed in the specification and claims as originally filed that is not adequately supported, either explicitly or implicitly, by the original disclosure.

Note also that MPEP §2163-2163.05 states, "See also *In re Smith*, 458 F.2d 1389, 1395, 173 USPQ 679, 683 (CCPA 1972) ('Whatever may be the viability of an inductive-deductive approach to arriving at a claimed subgenus, it cannot be said that such a subgenus is necessarily described by a genus encompassing it and a species upon which it reads.' (emphasis added))." See MPEP §2163.05(II). Analogously, in the instant case, the description of a broader range (i.e., "larger genus" of values) does not necessarily describe specific subgeneric ranges therein as now claimed by Applicant.

Considering the teachings provided in the specification as originally filed, Applicant has failed to provide the necessary teachings, by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams and formula that fully set forth the claimed invention in such a way as to reasonably convey to one skilled in the relevant art that Applicant had possession of the concepts of (1) zinc to be present in the composition in a concentration range from 10 μM to 10 mM (claims 24, 105 and 115), (2) zinc to be present in the composition in a concentration range of 900 μM to 10 mM (claims 35, 116 and 123), or (3) zinc to be present in the composition in a concentration range of 1 mM to 10 mM (claims 117 and 124).

Accordingly, the claims are considered to lack sufficient written description and are properly rejected under 35 U.S.C. 112, first paragraph.

Claim Rejections - 35 USC § 112, First Paragraph, Scope of Enablement

(New Grounds of Rejection)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 24-28, 30-31, 33, 35, 105, 107-109, 115-117 and 122-124 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the administration of the claimed zinc composition for increasing elastin content in the skin of a subject to treat wrinkles, does not reasonably provide enablement for the administration of the claimed zinc composition for increasing elastin content in the skin of a subject to prevent wrinkles. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art;
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,
8) the relative skill of those skilled in the art.

The relevant factors are addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The presently claimed invention is directed to a method for increasing elastin content in a region of skin of a subject, wherein the method comprises applying topically to the region of skin a composition consisting essentially of one or more zinc-containing components in admixture with a dermatologically or pharmaceutically acceptable carrier, in an elastin-increasing effective amount to the region of skin of the subject, wherein the zinc is selected from a variety of zinc salts, and the elastin content in the region of skin is increased in a sufficient amount to treat or prevent wrinkles.

In particular, one skilled in the art could not practice the presently claimed subject matter of preventing wrinkles via increasing the elastin content of a region of skin in a subject by topically applying the claimed zinc composition without undue experimentation because the artisan would not accept on its face that prevention of wrinkles via increasing elastin content of the skin could actually be accomplished given the state of the art at the time of the invention. Based upon the state of the art, as discussed below, and the evidence presented by Applicant, the artisan would have only accepted that wrinkles could be treated in a patient by increasing elastin content of the skin with the composition as instantly claimed.

As set forth in *In re Marzocchi et al.*, 169 USPQ 367 (CCPA 1971):

"[A] [s]pecification disclosure which contains the teachings of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with the enabling requirement of first paragraph of 35 U.S.C. 112, *unless there is reason to doubt the objective truth of statements contained therein which must be relied on for enabling support;* assuming that sufficient reasons for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in the specification is truly enabling." (emphasis added)

The present claims circumscribe the use of the presently claimed zinc composition for the treatment of patients for the purpose of increasing elastin content in a region of skin of the treated patient for the purpose of treating or preventing wrinkles in the patient. That is, in order to be enabled to practice the present invention, the skilled artisan would have to accept that by topical administration of the presently claimed zinc composition that the elastin content of the treated skin would have been sufficiently increased so as to prevent wrinkles from developing or worsening or that existing wrinkles would be eliminated. Because such preventive or curative success is not reasonably possible with most diseases or disorders, especially a condition as notoriously difficult to prevent as wrinkles and skin aging,

the specification, which lacks any direction or guidance as to how prevention or cure of wrinkles could actually be achieved, is viewed as lacking an enabling disclosure of the entire scope of the claimed invention.

Regarding the prevention or cure of wrinkles, the objective truth of the statement that such a condition may be prevented or cured is doubted because the limited number of effective treatment options poses a significant challenge to achieving the objective of prevention or the objective of curing the condition. In this regard, WrinkleReducer 101 is cited ("Preventing and Treating Skin Wrinkles", 2010) is cited and teaches, "A trip to the drug store is all you need to know, as there are countless anti-wrinkle creams on the market today. Some cost as little as $10 while others can run into the hundreds of dollars. The latest craze is skin resurfacing. Based on the theory that removing skin layers reduces wrinkles or irregular depressions, skin resurfacing can be done two different ways. Dermabrasion scrapes away the skin while chemical peels dissolve skin away. Researchers are always looking for more advanced wrinkle treatments. Laser skin resurfacing with an erbuim or carbon dioxide laser and Botox injections are the latest techniques developed to repair prematurely aged skin and wrinkles. It usually takes about four to six weeks to see results when you're using an over-the-counter wrinkle cream. The results will depend on the severity of your lines and wrinkles and how often you use the products. However, it's important to remember that there is no permanent solution to wrinkles. If you stop using the product that you have found effective, you'll soon notice the lines and wrinkles returning. Also, skin changes, so a product that once was effective may no longer be helpful. Age, environment and lifestyle changes can all impact the effectiveness of wrinkle removers. Skin wrinkles whether we want it to or not, but a careful skin care regimen can help to slow down the hands of time." (p.1-2)

Given that the art expressly acknowledges that known anti-wrinkled therapies are effective for reducing the incidence of wrinkles but have no effect on preventing them or eliminating them, the skilled artisan would not accept on its face Applicant's statement that skin elastin could be increased to the point

of preventing wrinkles because wrinkles are particularly difficult to effectively treat, especially using cosmetic or pharmacologic interventions, and further that it is clearly recognized in the art that wrinkles are processes of skin aging that cannot be stopped. Though the state of the art recognizes various anti-wrinkle strategies as providing the best possible option for treating wrinkles, it remains that what pharmacologic or cosmetic options are presently developed and available in the art are limited with regard to the degree of responsiveness they are able to elicit. Specifically, none of the present art-accepted therapies are capable of curing, stopping, eliminating or preventing wrinkles, but, at best, are capable of reducing the incidence of skin wrinkling, as evidenced by the above-cited reference. Such knowledge, therefore, casts doubt on the statement that the instantly claimed therapy is effective to increase elastin sufficiently such that skin wrinkles could be prevented from occurring or eliminated since the idea that the skilled artisan would be able to stop the process of skin aging and thereby prevent wrinkles would be an objective that would be difficult, if not impossible, to achieve without the expenditure of an undue level of experimentation. In light of such, the artisan would have required sufficient direction as to how the administration of the presently claimed composition could actually prevent skin wrinkling without requiring an undue level of experimentation such that the artisan would have been imbued with at least a reasonable expectation of success. Such success would not have been reasonably expected give that prevention or cure of this condition is an outcome not reasonably expected by one of ordinary skill in the art. Absent this disclosure, the present specification fails to enable the full scope of this invention as it relates to the objective of prevention or cure and, thus, fails to rebut the presumption of unpredictability in the art with regard to this same objective.

It is in this regard that Applicant is directed to the MPEP at §2164.08. All questions of enablement are evaluated against the claimed subject matter. Concerning the breadth of a claim relevant to enablement, the only relevant concern is whether the scope of enablement provided to one skilled in the art by the disclosure is commensurate with the scope of protection sought by the claims. The

determination of the propriety of a rejection based upon the scope of a claim relative to the scope of enablement involved the determination of how broad the claim is with respect to the disclosure and the determination of whether one skilled in the art is enabled to use the *entire scope* of the claimed invention without undue experimentation.

Applicant presents a working example in the instant specification of varying concentrations of zinc solutions applied topically to skin for the purpose of determining its effect on skin elasticity, wherein the tested concentrations of zinc demonstrated an increase in skin elastin. However, the specification fails to provide any working or prophetic examples of the instantly claimed zinc composition to demonstrate its ability of the composition to significantly increase elastin such that wrinkles could be effectively prevented or eliminated. While the lack of a working embodiment cannot be the sole factor in determining enablement, the absence of substantial evidence commensurate in scope with the presently claimed subject matter, in light of the unpredictable nature of the art and the direction that Applicant has presented, provides additional weight to the present conclusion of insufficient enablement in consideration of the *Wands* factors as a whole. The instant specification conspicuously lacks any disclosure or teaching of manner and process of using the presently claimed combination of compounds compound for achieving the objective of significantly increasing elastin in the skin such that wrinkles could be prevented or eliminated such that the skilled artisan would have been imbued with at least a reasonable expectation of success in achieving such an objective without the burden of an undue level of experimentation.

The basis for the present rejection is not simply that experimentation would be required, since it is clear from the state of the pharmaceutical and chemical arts that experimentation in this particular art is not at all uncommon, but that the level of experimentation required in order to practice this aspect of the invention in the absence of any enabling direction by Applicant would be *undue*. Please reference *In re Angstadt*, 537 F.2d 498, 504, 190 USPQ 214, 219 (CCPA 1976), which states, "The test of enablement is

not whether any experimentation is necessary, but whether, *if experimentation is necessary, it is undue*." (emphasis added)

In view of the discussion of each of the preceding seven factors, the level of skill in the art is high and is at least that of a medical doctor with several years of experience in the art.

As the cited art and discussion of the above factors establish, practicing the claimed method in the manner disclosed by Applicant would not imbue the skilled artisan with a reasonable expectation that the objective of administering the claimed zinc composition for increasing elastin content in the skin of a subject to prevent wrinkles could be accomplished. In order to actually achieve such a result, it is clear from the discussion above that the skilled artisan could not rely upon Applicant's disclosure as required by 35 U.S.C. 112, first paragraph, and would have no alternative recourse but the impermissible burden of undue experimentation in order to practice the full scope of the presently claimed invention.

Conclusion

Rejection of claims 24-28, 30-31, 33, 35, 105, 107-109, 115-117 and 122-124 is proper.

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie A. Royds/
Primary Examiner, Art Unit 1614

August 10, 2010